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PATENT TRADEMARK OFFICE

Docket No.: 1774/0K258

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mats ALLERS; Anders LUNDERQUIST; Fredrik BORIS-MOLLER;  
Tadeusz WIELOCH

Serial No.: 10/072,857

Art Unit: TBD

Confirmation No.: 2347

Filed: February 5, 2002

Examiner: TBA

For: CEREBRAL TEMPERATURE CONTROL

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, DC 20231

Sir:

Prior to examination on the merits, please amend the above identified application as follows:

IN THE SPECIFICATION

Pursuant to 37 C.F.R. § 1.121(b)(3), please replace the specification (not including the claims) with the substitute specification submitted herewith.

**IN THE CLAIMS:**

Please amend the claims pursuant to 37 C.F.R. 1.121 as follows (see the accompanying "marked up" version pursuant to 1.121):

Please amend the following claims:

1. (Amended) A method for brain hypothermia, said method comprising, in a first phase to enable an early and fast onset of the hypothermia, the steps of:

providing a container with an infusion solution having a first temperature and a venous infusion catheter connected to an outlet of said container, said venous infusion catheter having an infusion solution lumen;

percutaneously inserting a distal end of said venous infusion catheter into a peripheral vein;

cooling the infusion solution to a second temperature lower than said first temperature; and

infusing a first amount of said cold infusion solution into said vein via the infusion solution lumen of said venous infusion catheter shortly after said cooling, to enable the cold infusion solution to cool the blood flowing to the brain while avoiding air bubbles arising in the infusion solution.

7. (Amended) The method of claim 1, wherein said first amount of infusion solution is in the range of 1-2 liters.

28. (Amended) A method for brain hypothermia comprising, to enable a brain-selective hypothermia, the steps of:

providing a container with an infusion solution having a first temperature and an arterial infusion catheter connected to an outlet of said container, said arterial infusion catheter having an infusion solution lumen;

percutaneously inserting a distal end of said arterial infusion catheter into an artery in the vicinity of a branch artery supplying blood to the brain;

cooling the infusion solution to a second temperature lower than said first temperature; and

infusing an amount of said cold infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter shortly after said cooling, to enable the cold infusion solution to cool the blood flowing to the brain while avoiding air bubbles arising in the infusion solution and gaining an efficient temperature regulation of the brain.

35. (Amended) An equipment for brain hypothermia, said equipment comprising, to enable an early and fast onset of the hypothermia:

a container with an infusion solution having a first temperature and a venous infusion catheter being connectable to an outlet of said container, said venous infusion catheter having an infusion solution lumen;

said venous infusion catheter having a distal end devised to be percutaneously inserted into a peripheral vein;

a cooling device being configured for cooling the infusion solution to a second temperature lower than said first temperature.

41. (Amended) The equipment of claim 35, wherein said first amount of infusion solution is in the range of 1-2 liters.

63. (Amended) An equipment for brain hypothermia comprising, to enable a maintained hypothermia:

an extraction catheter configured to be inserted into a blood vessel for extraction of blood;

an arterial infusion catheter configured to be inserted in an artery in the vicinity of an artery supplying blood to the brain;

means for establishing an second extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a cooling device capable of cooling extracted blood;

a venous infusion catheter being configured to be inserted into a vein of the venous system;

means for establishing a first extra-corporeal blood circuit for heated blood between said extraction catheter and said venous infusion catheter via said pumping means and a heating device capable of heating extracted blood;

means for extracting blood from said blood vessel via said extraction catheter into said first and second extra-corporeal blood circuit;

a cooling device for cooling a second amount of said extracted blood;

a heating device for heating a first amount of said extracted blood;

and being configured to:

infusing said cooled second amount of extracted blood to said brain supplying artery via said arterial infusion catheter;

infusing said heated first amount of extracted blood to said venous system via said venous infusion catheter.

67. (Amended) The catheter of claim 65, having an outer diameter of about 2.7 millimeters, and wherein an inner diameter of said first lumen is about 2.1 millimeters and an inner diameter of said second lumen is about 0.3 millimeters.

68. (Amended) The catheter of claim 65, wherein said plurality of openings of said first lumen are arranged about 4 centimeters from the tip of the catheter, and said distal part tapers over a length of about 3 centimeters containing the second lumen.

Please add new claims 69-76:

69. (New) The method of claim 1, wherein the infusion solution is cooled to a second temperature in the range of 0 – 37 degrees Celsius, depending on the properties of pharmaceuticals contained in the infusion solution.

70. (New) The method of claim 1, further comprising the step of cooling the infusion solution in a cooling device immediately before infusion.

71. (New) The equipment of claim 35, wherein the cooling device is configured for cooling the infusion solution to a second temperature in the range of 0 – 37 degrees Celsius.

72. (New) The equipment of claim 45, further comprising:  
a temperature sensor being configured to be percutaneously inserted in a blood vessel draining blood from the brain;  
and being configured to:

sensing the temperature in the blood of said blood vessel thus providing an indication of the temperature in the brain;

adjusting the temperature of said cooled blood dependent on said sensed temperature for achieving a desired temperature in the brain.

73. (New) A method for delivery of an infusion solution comprising a pharmaceutical having brain protective properties, the method comprising the steps of:

providing a container with an infusion solution and an arterial infusion catheter connected to an outlet of said container, said arterial infusion catheter having an infusion solution lumen;

percutaneously inserting a distal end of said arterial infusion catheter into an artery in the vicinity of a branch artery supplying blood to the brain;

infusing an amount of said infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter to provide protection of the brain.

74. (New) The method as recited in claim 73, further comprising the steps of:

regulating the temperature of the infusion solution; and

infusing an amount of said temperature regulated infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter to enable the

temperature regulated infusion solution to regulate the temperature of the blood flowing to the brain and gaining an efficient temperature regulation of the brain.

75. (New) The method as recited in claim 74, further comprising the steps of:

cooling the infusion solution having a first temperature to a second temperature lower than said first temperature; and

infusing an amount of said cold infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter after said cooling, to enable the cold infusion solution to cool the blood flowing to the brain and gaining an efficient temperature regulation of the brain.

76. (New) The method as recited in claim 75, further comprising the step of infusing the amount of said cold infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter shortly after said cooling to avoid air bubbles arising in the infusion solution.




## REMARKS

The specification has been amended to correct spelling. Pending claims 1-68 have been amended to correct typographical errors. New claims 69-76 have been added. No new matter has been entered. The claims have not been amended or added for reasons related to patentability or narrowed by the amendments herein.

A prompt and favorable examination on the merits is earnestly solicited.

Dated: July 2, 2002

Respectfully submitted,

  
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Kevin L. Reiner  
Reg. No. 43,040  
Attorney for Applicant(s)

DARBY & DARBY P.C.  
Post Office Box 5257  
New York, NY 10150-5257  
212-527-7700

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Name (Print) D. DAVIS

Signature Davis

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MARKUP ACCOMPANYING PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, DC 20231

Sir:

IN THE SPECIFICATION

Please see the markup copy of the substitute specification filed herewith.

IN THE CLAIMS:

1. (Amended) A method for brain hypothermia, said method comprising, in a first phase to enable an early and fast [inset]onset of the hypothermia, the steps of:

providing a container with an infusion solution having a first temperature and a venous infusion catheter connected to an outlet of said container, said venous infusion catheter having an infusion solution lumen;

percutaneously inserting a distal end of said venous infusion catheter into a peripheral vein;

cooling the infusion solution to a second temperature lower than said first temperature; and

infusing a first amount of said cold infusion solution into said vein via the infusion solution lumen of said venous infusion catheter shortly after said cooling, to enable the cold infusion solution to cool the blood flowing to the brain while avoiding air bubbles arising in the infusion solution.

7. (Amended) The method of claim 1, wherein said first amount of infusion solution is in the range of 1-2 [litres] liters.

28. (Amended) A method for brain hypothermia comprising, to enable a brain-selective hypothermia, the steps of:

providing a container with an infusion solution having a first temperature and an arterial infusion catheter connected to an outlet of said container, said arterial infusion catheter having an infusion solution lumen;

percutaneously inserting a distal end of said arterial infusion catheter into an artery in the vicinity of a branch artery supplying blood to the brain;

cooling the infusion solution to a second temperature lower than said first temperature; and

infusing an amount of said cold infusion solution into said artery via the infusion solution lumen of said arterial infusion catheter shortly after said cooling, to enable the cold infusion solution to cool the blood flowing to the brain while avoiding air bubbles arising in the infusion solution and gaining an efficient temperature regulation of the brain.

35. (Amended) An equipment for brain hypothermia, said equipment comprising, to enable an early and fast [inset]onset of the hypothermia:

a container with an infusion solution having a first temperature and a venous infusion catheter being connectable to an outlet of said container, said venous infusion catheter having an infusion solution lumen;

said venous infusion catheter having a distal end devised to be percutaneously inserted into a peripheral vein;

a cooling device being configured for cooling the infusion solution to a second temperature lower than said first temperature.

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41. (Amended) The equipment of claim 35, wherein said first amount of infusion solution is in the range of 1-2 [litres] liters.

63. (Amended) An equipment for brain hypothermia comprising, to enable a maintained hypothermia:

an extraction catheter configured to be inserted into a blood vessel for extraction of blood;

an arterial infusion catheter configured to be inserted in an artery [into]in the vicinity of an artery supplying blood to the brain;

means for establishing an second extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a cooling device capable of cooling extracted blood;

a venous infusion catheter being configured to be inserted into a vein of the venous system;

means for establishing a first extra-corporeal blood circuit for heated blood between said extraction catheter and said venous infusion catheter via said pumping means and a heating device capable of heating extracted blood;

means for extracting blood from said blood vessel via said extraction catheter into said first and second extra-corporeal blood circuit;

a cooling device for cooling a second amount of said extracted blood;


means for extracting blood from said blood vessel via said extraction catheter  
into said first and second extra-corporeal blood circuit;  
a cooling device for cooling a second amount of said extracted blood;  
a heating device for heating a first amount of said extracted blood;  
and being configured to:  
infusing said cooled second amount of extracted blood to said brain supplying  
artery via said arterial infusion catheter;  
infusing said heated first amount of extracted blood to said venous system  
via said venous infusion catheter.

67. (Amended) The catheter of claim 65, having an outer diameter of about  
2.7 [millimetres] millimeters, and wherein an inner diameter of said first lumen is about  
2.1[millimetres] millimeters and an inner diameter of said second lumen is about 0.3  
[millimetres] millimeters.

68. (Amended) The catheter of claim 65, wherein said plurality of openings of said first lumen are arranged about 4 [centimetres] centimeters from the tip of the catheter, and said distal part tapers over a length of about 3 [centimetres] centimeters containing the second lumen.

Dated: July 2, 2002

Respectfully submitted,

  
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Kevin L. Reiner  
Reg. No. 43,040  
Attorney for Applicant(s)

DARBY & DARBY P.C.  
Post Office Box 5257  
New York, NY 10150-5257  
212-527-7700